

From: Ruane, Patrick J.
To: Kaufman, Keith D.; Round, Elizabeth M.
Cc: Terranella, Lisa A.
Subject: Phase III Drug Related Sexual AEs

Keith and Betty,

I've reviewed the drug related sexual AEs for years 3-5 and have the following summary:

During Years 3 -5 in the Phase III Pivotal Studies, 6 patients who were taking finasteride 1 mg discontinued due to drug-related sexual adverse experiences. The AEs for 5 patients resolved. For one patient, AN 1125 from Dr. Rittmaster's site, the AE (erectile dysfunction) was still continuing when he discontinued the study. At the time of his discontinuation visit, he was off therapy for 66 days. It does not look like the patient was contacted for resolution of the AE .

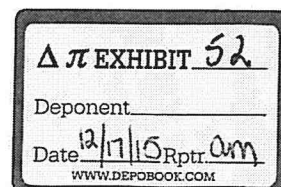
During Years 3 -5 in the Phase III Pivotal Studies, 23 patients who were taking finasteride 1 mg experienced drug-related sexual adverse experiences. Of these 23 patients, the AEs for 7 patients were still present when they discontinued/completed the study. Of the 16 patients who had AEs resolve, the AEs for 7 patient resolved while on therapy and the AEs for 9 patients resolved while off of therapy.

I am planning on trying to determine as to whether the patients who's AEs were still present were contacted for resolution.

Patrick

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